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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,732	07/31/2001	Piero Anversa	674554-2002	6924

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,732	ANVERSA, PIERO	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-153* is/are pending in the application.

4a) Of the above claim(s) *1-25,53-123 and 141-153* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-52 and 124-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/04/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 11/17/03 has been entered.

Claims 1-153 are pending in the present application, with amended claims 26-52 and 124-140 are presently under examination and stem cell factor as an elected species of cytokine.

This application contains claims 1-25, 53-123 and 141-153 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The references listed in the information disclosure statement filed 11/17/03 have not been considered as to the merits, because there is no evidence of record indicating that the references have been received by the Office, nor any of the references has been scanned for this IFW application.

Request for Interview

The request for an interview, with "supervisory review", prior to issuance of any paper other than a Notice of Allowance, is denied because Applicants fail to point out any specific issues to be discussed. Furthermore, this amended case has to be acted by 2/6/04.

Claim Rej ctions - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 26-52 and 124-140 are rejected under 35 U.S.C. 102(b) as being anticipated by Isner et al. (WO 99/45775) for the same reasons already set forth in the previous Office Action mailed 6/17/03 (pages 5-6).

Isner et al. disclose a method for forming new blood vessels or preventing or reducing the severity of blood vessel damage associated with ischemia or related conditions in a mammal comprising administering to the mammal an effective amount of a vascularization agent such as Stem cell factor (SCF, also known as Steel factor), GM-CSF, VEGF and others (See Summary of the Invention, pages 4-12). Conditions that are conducive to damaging blood vessels include ischemic vascular diseases such as ischemic cardiomyopathy, myocardial ischemia, limb ischemia; and that ischemia may especially adversely impact heart or brain tissue as often occurs in cardiovascular disease or stroke, respectively (page 15, lines 1-10). The vascularization agent can be administered into a human patient in need of treatment through various routes including subcutaneous, intravenous, intraarterial, intramuscular and intraperitoneal (page 18, lines 14-19). Isner et al. further teach that the preferred *in vivo* dosages for the vascularization agents are from about 1μg/kg/day to about 100 μg/kg/day (page 19, lines 2-3).

Since the methods taught by Isner et al. have the same step (administration of SCF at an effective amount from about 1μg/kg/day to about 100 μg/kg/day) as the presently claimed methods, they also inherently stimulate or mobilize the treated patient's own somatic stem cells.

Accordingly, Isner et al. anticipate the instant claims.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed 11/17/03 (pages 21-22) have been fully considered, but they are not found persuasive.

Applicants argue basically that Isner describes only neovascularization, not the repair of damaged myocardial tissue, and that Isner is concerned only with the blood vessels themselves, not the surrounding tissue damaged by the lack of oxygen. Applicants further direct the examiner's attention towards page 16 of Isner, wherein it states "[a]s described above and in the examples following, we have discovered means to promote angiogenesis and reendothelialize denuded blood vessels in mammals." and "for enhancing angiogenesis in a selected patient having an ischemic tissue", and argue that while the methods are directed at patients who have suffered ischemic tissue damage, Isner/s methods only provide stimulation of angiogenesis in order to retard further tissue damage. In contrast, the present invention provides for the actual repair of ischemic tissue, including myocardium, and therefore Isner can not anticipate the presently claimed invention.

Applicants' arguments are respectfully found to be unpersuasive for the following reasons.

Isner et al. disclose clearly a method for forming new blood vessels or preventing or reducing the severity of blood vessel damage associated with ischemia including ischemic vascular diseases such as ischemic cardiomyopathy, myocardial ischemia in a mammal comprising administering to the mammal an effective amount of a vascularization agent such as Stem cell factor (SCF, also known as Steel factor), GM-CSF, VEGF and others at an effective amount from about 1μg/kg/day to about 100 μg/kg/day. Since the method taught by Isner has the same step, same starting materials (administration of SCF at an effective amount from about 1μg/kg/day to about 100 μg/kg/day into a mammal suffering from ischemic vascular diseases including ischemic cardiomyopathy or myocardial ischemia) as the presently claimed methods, it is inherent that the method of Isner would also stimulate or mobilize the treated mammal's own somatic stem cells, including and not necessarily limited only to endothelial progenitor cells taught by Isner, to repair damaged myocardium and/or myocardial cells or for depositing the somatic stem cells in a cardiac or blood vessel tissue (see claim 124). In other words, the presently claimed method is not distinguishable from the method taught by Isner.

Accordingly, the instant claims are still rejected under 35 U.S.C. 102(b) as being anticipated by Isner et al. (WO 99/45775) for the reasons already set forth above.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER